HELICAL STENT

This invention relates to stents for insertion in a
5   fluid conduit of the human or animal body.
Stents are generally tubular devices used for
providing physical support to blood vessels, i.e. they
can be used to help prevent kinking or occlusion of
blood vessels such as veins or arteries and to prevent
10   their collapse after dilatation or other treatment.
Stents can be broadly divided into two main
categories: balloon expandable stents and self-expanding
stents. In the case of the former the material of the
stent is plastically deformed through the inflation of a
15   balloon, so that after the balloon is deflated the stent
remains in the expanded shape. Such stents are
manufactured in the "collapsed" condition, ready for
delivery, and may be expanded to the expanded condition
when inside the vessel or other fluid conduit.
20   Self-expanding stents are also designed to be
delivered in the collapsed condition and when released
from a constraining delivery system the stent expands to
its expanded condition of a predetermined size. This
effect is achieved by using the elasticity of the
25   material and/or a shape-memory effect. In the case of
shape-memory stents a commonly used material is nitinol.
Many different designs of stents are available on
the market. They are made from a variety of materials
providing corrosion resistance and biocompatibility.
30   They are made from sheet, round or flat wire or tubing.
They are generally cylindrical but also longitudinally
flexible so as to conform to the curvature of the fluid
conduit into which they are inserted.
It has been proposed in EP 1042997 to provide
35   stents the flexibility of which varies along their
length, in order to facilitate placement of one end of
the stent in a narrower or tortuous coronary artery, or

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to achieve stenting of a bend of a particular coronary
artery. This proposal involves providing the stent with
a pattern of interconnected struts, with the strut
thickness being variable along the length of the stent.

5   We have previously proposed that the flow pattern
in arteries including the swirling pattern induced by
their non-planar geometry operates to inhibit the
development of vascular diseases such as thrombosis,
atherosclerosis and intimal hyperplasia.

10   In WO 98/53764, there is disclosed a stent for
supporting part of a blood vessel. The stent includes a
supporting portion around which or within which part of
a blood vessel intended for grafting can be placed so
that the stent internally or externally supports that

15   part. The supporting portion of the stent is shaped so
that flow between graft and host vessel is caused to
follow a non-planar curve. This generates a swirl flow,
to provide a favourable blood flow velocity pattern
which reduces the occurrence of vascular disease,

20   particularly intimal hyperplasia.

        In WO 00/32241, there is disclosed another type of
stent, in this case including a supporting portion
around which or within which part of an intact blood
vessel other than a graft can be placed. This

25   supporting portion can prevent failure of the vessel
through blockage, kinking or collapse. Again, the
supporting portion of the stent is of a shape and/or
orientation whereby flow within the vessel is caused to
follow a non-planar curve. Favourable blood flow

30   velocity patterns can be achieved through generation
therein of swirl flow within and beyond the stent.
Failures in blood vessels through diseases such as
thrombosis, atherosclerosis, intimal hyperplasia can
thereby be significantly reduced.

35   Further aspects of how swirl flow is beneficial are
explained in the above publications. It is further
explained in Caro et al. (1998) J. Physiol. 513P,2P how

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non-planar geometry of tubing inhibits flow instability.

It has been proposed in WO 00/38591 to provide a
stent with internal helical grooving or ridging to
induce helical flow. Figures 9 to 12 of this document
5   show a stent in the form of a mesh cylinder, with vane
members attached to the inside of the cylinder so as to
project into the fluid passage and guide the flow.
However the presence of vanes projecting into the flow
may obstruct the flow and increase flow resistance,
10   especially if there is any build-up of material on the
vanes. Also, the use of vanes in an otherwise
cylindrical tube may not reliably induce swirl flow
across the entire cross-section of flow. There may be a
tendency for the flow nearer to the centre of the tube
15   to follow a linear path, particularly for flows at
higher Reynolds numbers. Further, the provision of
vanes over a relatively short length of flow is likely
to create only a temporary alteration of flow
characteristics, with the flow reverting to a normal
20   pattern at a distance downstream of the vanes.

In WO 02/098325 there are various proposals for
cylindrical external structures for placement outside of
blood flow conduits in order to influence the internal
geometry of the conduit lumen. By providing ribs or
25   other radially inwardly projecting helical members, the
cross-sectional shape of the lumen is modified from the
outside of the conduit. The various structures are not
for use as stents capable of delivery internally of a
conduit in a collapsed condition and for expansion at
30   the target site.

In WO 00/32241 internal stents for establishing
and/or maintaining non-planar curvature of a blood
vessel are shown. Figure 5 of this document shows a
clip which is part coiled or at least part helical of
35   shape memory alloy, affixed to a cylindrical wire mesh.
With such an arrangement, when the clip moves to a more
coiled condition once the stent has been installed, it

will cause the cylindrical wire mesh to adopt a non-planar curvature but it will also cause it to twist. Since it is undesirable for the stent to apply torsional loading to the inside wall of the blood vessel, this

5   twisting effect may limit the number of helical turns imposed by the clip, for example to one or less than one turn. However, the objective of inducing or maintaining swirl flow in the vessel is assisted by increasing the number of helical turns. The clip also forms a rib

10   projecting into the flow lumen of the blood vessel which, as discussed above in relation to vane members, may not be ideal for the flow characteristics of the vessel.

We have now found a way of producing an internal

15   stent capable of moving from a collapsed condition to an expanded condition without significant twisting but which facilitates flow within the stent supported fluid conduit to follow a non-planar curve, i.e. to swirl.

According to a first aspect of the invention there

20   is provided a stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising an outer wall for engagement with the conduit, the outer wall having a

25   helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the stent from the collapsed condition to the expanded condition resists extension.

Flow within the fluid conduit supported by such a

30   stent can follow a non-planar curve, promoting swirl flow, the benefits of which are discussed above. Thus, considering the flow lumen of the conduit, as this extends in the longitudinal direction (x-axis) it curves in more than one plane (i.e. in both the y-axis and the

35   z-axis). In other words, the flow lumen extends generally helically in the longitudinal direction. Such a non-planar curve may be achieved by a non-rotationally

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symmetric shape (rotational symmetry of order one) when
in the expanded condition, which "twists" along the
length of the stent. It may however also be achieved if
the stent has a circular or other rotationally

5   symmetrical cross-sectional shape, providing the cross-
section as a whole shifts laterally from one "slice" to
the next. In some instances, a combination of a non-
rotationally symmetric shape which twists and which
shifts laterally is provided.

10   Preferably, when the stent is in its expanded
condition, it causes the fluid conduit to follow a non-
planar curve as it extends in the longitudinal direction
and the curve undergoes at least one turn. The
provision of more than one turn, more preferably a

15   plurality of turns, is enabled by the ability of
preferred stents to expand from the collapsed condition
to the expanded condition without substantial twisting,
i.e. there is no significant rotation of one end of the
stent relative to the other. This can be achieved by

20   the helical portion having the same number of turns both
when the stent is collapsed and when it is expanded.
This property of the stent means that it can expand
without causing the conduit to twist, which would be
undesirable because of the tethering of the conduit in

25   the human or animal body.
          Preferably, the centre line of the stent in the
expanded condition follows a substantially helical path.
In other words, the centroids of adjacent cross-
sectional slices through the stent define a helical

30   locus or centre line.
          It is generally preferred to avoid any pronounced
grooves, ridges, ribs or vanes, as these may have the
opposite of the desired effect of improving flow
characteristics, i.e. they may obstruct the flow,

35   facilitate deposit build up or create stagnant regions.
Preferably, therefore, the stent is substantially free
of ribs or vanes, for example free of thicker wires

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(than adjacent wires) which would act as a rib
projecting into the flow lumen of the flexible conduit.

The stent improves flow characteristics. As is
well known, in the case of straight tubes, near wall
5   velocities are very low compared to velocities at the
core of the tube, due to the effects of viscosity. In
the case of tubes which are bent in a single plane, the
speed of the flow at the outside of the bend is
increased but the speed of the flow at the inside is
10   retarded further. In both cases, there is considerable
variation in axial velocity across the width of the
tube. With the use of a helical tubing portion
according to the invention, a swirl flow is generated
and the axial velocity profile of the flow across the
15   tubing portion becomes generally more uniform or
"blunter", with the axial velocity of flow at both the
outside and inside of the tubing portion being closer to
the mean axial velocity.

Thus, the flow characteristics are improved by
20   causing swirling and a relatively uniform distribution
of axial and near wall velocity. Mixing over the cross
section is also promoted and there is a reduction in the
likelihood of occurrence of flow instability. The
avoidance and flushing of stagnant zones is assisted.
25   There is a reduction in the potential for deposit build
up within and downstream of the graft and the
development of pathology.

The amplitude and pitch of the helical centre line
may be chosen to vary along the length of the stent, if
30   desired. Variation of amplitude can be achieved by
increasing or decreasing the resistance to extension
provided by the helical portion, whilst variation in
pitch may be achieved by varying the pitch of the
helical portion itself. Such variations may for example
35   be desired if it is wished to introduce a gentle swirl
at the upstream end of the stent and to increase the
swirl effect in the downstream direction.

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        The stents of the preferred embodiments have a
helical portion which has a greater resistance to
extension than portions of the stent adjacent to the
helical portion. Preferably, the helical portion
5   comprises an increased amount of stent forming material
relative to the amount of stent forming material in
portions of the stent adjacent to the helical portion.
The increased amount of material can provide the
required resistance to extension when the stent expands
10   to the expanded condition. The increase may be provided
for example by thicker structural members, in the radial
direction and/or longitudinal direction and/or
circumferential direction. The increased amount may
alternatively or additionally be provided by the use of
15   extra stent forming members. For example, in the case
of a woven stent, the helical portion may be provided by
weaving in one or more extra wires. In other cases,
extra struts may be provided.
        The helical portion may comprise structural members
20   having bent portions which resist unbending during
expansion of the stent. Many stents consist of
structural members bent between nodes or at nodes. In
general, when the stent expands some or all of the bent
portions unbend as the diameter of the stent increases.
25   The desired resistance to extension may therefore be
achieved by the helical portion having structural
members with bent portions which resist unbending more
than bent portions adjacent to the helical portion.
        The helical portion may be arranged to resist
30   extension in the circumferential direction, or to resist
extension in the longitudinal direction, or to resist
extension in the circumferential and the longitudinal
directions. The choice of the appropriate form of the
helical portion will generally depend on the type of
35   stent and the manner in which it expands.
        The helical portion may be viewed as a helical
stripe extending longitudinally and circumferentially of

the stent. The stripe may be substantially continuous,
as for example in the case of one or more extra wires
woven into the stent, or it may be discontinuous, as
will be the case where the stent has thicker or

5   otherwise modified structural members which are
separated by spaces.

        The stent may be of the self-expanding type or it
may be balloon expandable. In the case of self-
expanding stents, during expansion from the collapsed

10   condition to the expanded condition, the portions which
are not part of the helical portion will be seeking to
expand due to their elasticity or shape-memory
properties. The expansion is resisted in the vicinity
of the helical portion by being less expansible. The

15   helical portion may itself extend to some degree during
expansion of the stent, and indeed may itself be seeking
to expand due to its elasticity or shape-memory
properties. However, the rest of the stent will be
seeking to expand more than the helical portion so that

20   in effect the helical portion provides a resistance to
extension. This will enable the stent to assume the
desired shape for promoting swirl flow in a fluid
conduit supported by the stent.

        In the case of a balloon expandable stent, the

25   force to expand the stent is supplied by the balloon and
the helical portion will allow less expansion, which
will normally mean a lesser degree of plastic
deformation, than the rest of the stent.

        The basic geometry of the stent may be of the many

30   available types, such as coil stents, helical spiral
stents, woven stents, sequential ring stents, closed
cell sequential ring stents, and open cell stents. They
may be made by coiling, braiding or knitting wires, by
laser cutting from tubing, by electric discharge milling

35   (EDM), by chemical etching or by other known methods.
They may be made from a variety of materials, including
stainless steel, nitinol, tantalum, platinum iridium,

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niobium alloy, cobalt alloy or polymers (such as
biodegradable polymers).

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According to a second aspect of the invention there
is provided a balloon expandable stent for insertion in
a fluid conduit of the human or animal body when the
stent is in a collapsed condition and for expansion to
an expanded condition, the stent comprising a balloon
having an expandable wall, the wall having a helical
portion which in the expanded condition extends
10
longitudinally and circumferentially, and which, upon
expansion of the balloon from the collapsed condition to
the expanded condition, resists extension.

In some circumstances the main stent body, i.e.
that which is left in the fluid conduit after the
15
balloon is removed, may be of a conventional type before
expansion. After expansion, however, it retains (by
plastic deformation) a shape which corresponds to that
determined by the balloon with the helical portion of
reduced extensibility.

20
Alternatively, the stent may have an outer wall for
engagement with the fluid conduit in accordance with the
first aspect of the invention, i.e. also with a helical
portion which resists extension. The helical portions
of the balloon and the stent outer wall would then
25
preferably be arranged in registration with each other.

The helical portion of the balloon expandable wall
may have a wall thickness greater than that of adjacent
wall portions. This could easily be achieved by adding
a helical "stripe" around the outside of a balloon of
30
uniform wall thickness, thereby creating the thicker
helical portion.

In certain aspects, the invention is concerned with
stents for insertion in flexible conduits of the human
or animal body, in which a helical centre line of the
35
flow lumen of the conduit is of relatively small
amplitude.

A further proposal in WO 00/38591 is to provide a

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circular-section tube bent into a cork screw shape. It
is usual for the helix of a cork screw to have a clear
gap down the middle, so that this proposed configuration
would have a wide swept width compared to the width of
the tubing, certainly more than two tubing diameters.
The amplitude of the helix would be greater than one
half of the internal diameter of the tubing and there
would be no "line of sight" along the inside of the
tubing. This proposal would therefore be relatively
bulky and unsuitable for certain applications. A
similar proposal is shown in Figure 5 of WO 02/98325,
relating to a tubular mesh structure to be located
externally of a conduit, the tubing having a helix with
a large amplitude and again no "line of sight" along the
inside of the tubing.

        According to a third aspect of the invention, there
is provided a stent for insertion in a fluid conduit of
the human or animal body when the stent is in a
collapsed condition and for expansion to an expanded
condition, wherein in the expanded condition the stent
causes the fluid conduit to have a flow lumen having a
centre line which follows a substantially helical path,
the helical centre line having a helix angle less than
or equal to 65° and an amplitude less than or equal to
one half of the internal diameter of the flow lumen.

        The features of the third aspect above, and its
preferred features below, may also be useful in
conjunction with the stents in accordance with the first
or second aspects of the invention, individually or in
combinations.

        The invention is applicable to stents internal to
intact blood vessels or blood vessels intended for
grafting.

        In this specification, the amplitude of the helix
refers to the extent of displacement from a mean
position to a lateral extreme. So, in the case of the
flow lumen having a helical centre line, the amplitude

is one half of the full lateral width of the helical
centre line.

In the flow lumen, in which the amplitude of the
helix is less than or equal to one half of the internal
diameter of the tubing, there is a "line of sight" along
the lumen of the tubing, unlike in the case of a
corkscrew configuration where in effect the helix is
wound around a core (either solid, or "virtual" with a
core of air). We have found that the flow at the line
of sight generally has a swirl component, even though it
could potentially follow a straight path.

For the purposes of this specification, the term
"relative amplitude" of a helical flow lumen is regarded
as the amplitude divided by the internal diameter. So,
in the flow lumen in which the amplitude of the helical
tubing is less than or equal to one half of the internal
diameter of the tubing, this means that the relative
amplitude is less than or equal to 0.5. Relative
amplitudes less than or equal to 0.45, 0.4, 0.35, 0.3,
0.25, 0.2, 0.15 or 0.1 may be preferred in some
circumstances. It is however preferred for the relative
amplitude to be at least 0.05, more preferably 0.1.
This can help to ensure that the desired swirl flow is
induced.

The relative amplitude may vary according to the
use of the stent and the spatial constraints on its
design. It will however be appreciated that by keeping
the amplitude less than half the tubing internal
diameter a swirling flow may be induced without creating
an excessively large device. The "envelope" occupied by
the stented conduit can fit into the space available in
the tissue surrounding the fluid conduit, and even if
this envelope is caused to follow a particular path by
the local environment in which the conduit is located,
the desired helical geometry of the flow lumen can be
maintained.

It is expected that the conduit may prevent the

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stent from expanding to its full size. Therefore, the
stent may be designed to have a relative amplitude
greater than 0.5 (e.g. 0.6 or 0.7), but so that in use a
relative amplitude of the flow lumen is equal to or less
than 0.5. In certain preferred arrangements, however,
the relative amplitude of the expanded stent *ex vivo* is
less than or equal to 0.5.

The angle of the helix is also a relevant factor in
balancing the space constraints on the flow tubing with
the desirability of maximising the cross-sectional area
available for flow. The helix angle is less than or
equal to 65°, preferably less than or equal to 55°, 45°,
35°, 25°, 20°, 15°, 10° or 5°. As with relative
amplitudes, the helix angle may be optimized according
to the conditions: viscosity, density and velocity of
fluid.

Generally speaking, for higher Reynolds numbers the
helix angle may be smaller whilst satisfactory swirl
flow is achieved, whilst with lower Reynolds numbers a
higher helix angle will be required to produce
satisfactory swirl. The use of higher helix angles will
generally be undesirable, as there may be near wall
pockets of stagnant fluid. Therefore, for a given
Reynolds number (or range of Reynolds numbers), the
helix angle will preferably be chosen to be as low as
possible to produce satisfactory swirl. Lower helix
angles result in smaller increases in length as compared
to that of the equivalent cylindrical tubing. In
certain embodiments, the helix angle is less than 20° or
less than 15°.

It will be appreciated that in pulsatile flow, the
Reynolds number will vary over a range. Typical mean
resting arterial blood flow Reynolds numbers are about
100, reaching peak values of two or three times that in
pulsatile flow and three to four times the mean during
exertion. Therefore the extent to which swirl flow is
promoted will vary likewise. Even if there are stagnant

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flow regions at lower Reynolds numbers, because for
example a low helix angle and/or a low relative
amplitude has been selected, these will tend to be
flushed out during periods of flow when the Reynolds
numbers are higher.

The stent may be made with substantially the same
relative amplitude and helix angle along its length.
There may be small variations when the stent is in use,
caused by elongation or contraction of the tubing
portion due to tensile loading or caused by torsional
loading. However, there may be circumstances in which
the stent has a variable helix angle and/or relative
amplitude, either to suit the space constraints or to
optimise the flow conditions.

For reasons of manufacturing simplicity, it may be
preferred for the stent to have a substantially constant
cross-sectional area along its length. Again, there may
be variations in use caused by loading on the stent.

The helical part of the stent may extend along just
part of the overall length of the stent or it may extend
over substantially its entire length. For example, a
stent may have a part with the geometry of the invention
over part of its length or over substantially its entire
length.

The stent may undergo a fraction of one complete
turn, for example one quarter, one half or three
quarters of a turn. Preferably, the stent undergoes at
least one turn, more preferably at least a plurality of
turns. Repeated turns of the helix along the stent will
tend to ensure that the swirl flow is generated and
maintained.

The stent may extend generally linearly. In other
words, the axis about which the centre line of the stent
follows a substantially helical path, may be straight.
Alternatively the axis may itself be curved, whereby the
envelope occupied by the stented conduit is curved, for
example to produce an "arch" shaped conduit. The bend

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of the arch may be planar or non-planar, but should preferably be such that swirl is maintained and not cancelled by the geometry of the bend. Thus, for example, a stent may be generally "arch" shaped (planar or non-planar), having the geometry in accordance with the third aspect of the invention, i.e. such that the stented conduit follows a substantially helical path with a helix angle less than or equal to 65°, and with an amplitude less than or equal to one half of the internal diameter of the tubing portion.

The stent may if desired comprise a pharmaceutical coating. Such a coating could be provided to provide sustained release of the pharmaceutical over a period of time. So, the stent could provide a pharmaceutical for initial treatment of a disease, and in the longer term the stent gives a therapeutic benefit due to the characteristics which it imparts to the flow.

In the above prior art proposals using multiple grooves or ridges arranged about the tubing circumference, or non-circular sections which are twisted, where the tubing is substantially straight, then the centre line of the tubing is also straight. This is unlike the centre line of the stent of the present invention, in its third aspect, which follows a substantially helical path. Thus, the stent may have a substantially circular cross-section and thus the smallest possible wetted perimeter to cross-sectional area ratio, whilst still having the necessary characteristics to induce swirl flow. Of course, there may be circumstances in which the stent has a non-circular cross-section, for example to assist interfacing or where pressure loss considerations are not significant.

There are proposals in WO 97/24081 and EP 1127557 A1 for tubing to have a single internal rib arranged helically. This results in the tubing having a centre line which follows a helical path, but because the rib

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is provided in an otherwise cylindrical tube, the
amplitude of the helix is very small, generally having a
relative amplitude appreciably less than 0.05. The
generation of swirl flow, if there is any, is
5   correspondingly limited and unsatisfactory.

Further concerning the prior art proposals using
grooves or ridges or ribs, it should be noted that
arterial geometry is under normal physiological
conditions non-planar (i.e. curved in more than one
10   plane in the nature of a helix) and not grooved or
rifled. We have found experimentally that at higher
relevant Reynolds numbers, the flow in a helical (non-
planar) geometry differs from that in a rifled/grooved
geometry, e.g. there is swirling of both near-wall flow
15   and core flow in the former case. The development of
swirl flow is more rapid than in the case of
rifled/grooved tubing, where swirl flow can take many
tubing diameters to develop. Thus, there is the
expectation that the introduction of the physiological
20   non-planar geometry (unlike grooved or rifled geometry)
will be beneficial in respect of inhibiting the
development of pathology.

Because the stent of the third aspect of the
invention has a helical centre line, there is spatial
25   reorganisation of vortical structures, which results in
motion of the core or cores of the axial flow across the
section of the stent, promoting mixing across the cross
section. The swirl inhibits the development of
stagnation and flow separation regions and stabilises
30   flows.

As mentioned, in the case of the prior art
proposals using multiple grooves or ridges or ribs, or
twisted tubes of a non-circular cross-section, the
centre line is straight, not helical. Whilst this can
35   be expected to stabilise flow at sharp bends, it does
not in straight tubes cause spatial reorganisation of
vortical structures, resulting in motion of the core or

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cores of the axial flow across the section of the tube.
Thus it does not promote mixing across the cross section
to the same extent as tubing according to the invention.
Such mixing may be important in maintaining the mass
5   transport and physiological integrity of the blood
vessels.

        The stent geometry disclosed herein may be used in
various biomedical applications e.g. in various arteries
(such as in the coronary, carotid and renal arteries),
10   in veins, and in non-cardiovascular applications such as
in the gastro-intestinal (e.g. bile or pancreatic
ducts), genito-urinary (e.g. ureter or urethra) or the
respiratory system (lung airways). Thus, the invention
extends to stents for body fluids other than blood. In
15   general, the use of the geometry of the invention can
avoid the presence of stagnant regions, and hence be
beneficial.

        Certain preferred embodiments of the invention will
now be described by way of example and with reference to
20   the accompanying drawings, in which:

        Figure 1 is a perspective view of a first
embodiment of stent in accordance with the invention;

        Figure 2 is a longitudinal cross-sectional of the
stent;

25   Figure 3 is a transverse cross-sectional view of
the stent on the line III-III of Figure 2;

        Figure 4 is a longitudinal cross-sectional view of
a second embodiment of stent;

        Figure 5 is a transverse cross-sectional view of
30   the second embodiment on the line V-V of Figure 4;

        Figure 6 is a fragmentary longitudinal cross-
sectional view of a third embodiment of stent;

        Figure 7 is a fragmentary view of a longitudinal
cross-section of a fourth embodiment of stent;

35   Figure 8 is a view of an experimental balloon;

        Figure 9 is a view of another experimental balloon;

        Figure 10 is a side view of part of a balloon

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expandable stent, before expansion;

Figure 11 is an elevation view of a tubing portion having a flow lumen in accordance with certain aspects of the invention;

5   Figure 12 shows elevation views of tubing portions used in experiments;

Figure 13 shows elevation views of tubing portions used in further experiments;

Figure 14 is a perspective view of a stent;

10   Figure 15 is a perspective view of another stent;

Figure 16 is a perspective view of the stent of Figure 15 internally supporting an arterial graft part; and

Figure 17 is a perspective view of an internal

15   arterial stent.

Figures 1 to 3 show a woven stent 2 in the expanded condition. The stent has the usual wire strands 4 arranged in a mesh and collectively forming a mesh like outer wall 7. It is also provided with a helical

20   portion or "stripe" 6 extending longitudinally and circumferentially of the stent. The helical portion 6 in this case consists of two additional strands 8 woven into the main mesh.

One effect of the helical portion 6 is to create a

25   cross-sectional shape approximating to a circle with a segment removed in the region corresponding to the helical portion, as seen in Figure 3. This cross-sectional shape has a centroid 9. The locus of centroids 9 along the length of the stent defines a

30   helical centre line 40, shown in Figure 1. The centre line 40 follows a helical path about a longitudinal axis 30 which is at the centre of an imaginary cylindrical envelope 20 within which the stent is contained. The amplitude A of the helix is shown in Figure 1.

35   In practice the amplitude A is greater than would be achieved by merely rotating the cross-sectional shape about the centre of the circle 3. In that case, the

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envelope 20 would simply correspond to the circle 3.
However, the effect of the helical portion resisting
extension during expansion is to cause the envelope 20
to be appreciably larger than the circle 3. This is
5   another effect of the helical portion contributing to
the creation of a non-planar or helical flow lumen.

In use, the stent is deployed at a target site and
is then expanded by a balloon or by the elasticity or
shape-memory properties of the strands 4. The helical
10   portion 6 acts to restrict extension (at least in the
longitudinal direction) and hence the expanded stent
adopts the configuration described, in which the centre
line of the stent follows a helical path. The outer
wall 7 engages the fluid conduit wall and influences its
15   shape so that the lumen of the fluid conduit at the
target site also tends to have a helical centre line.
This will help to promote swirl flow along the lumen.
The handedness ("s" or "z") of the stent will normally
be chosen to complement the local fluid conduit geometry
20   so as to enhance any swirl flow already existing
upstream of the stent and not to cancel it.

In the embodiment shown in Figures 1 to 3 two
helically arranged wires 8 are provided, but other
numbers of wires could be used. In addition, the wires
25   could be designed to provide the greatest resistance to
extension in the middle of the helical portion 6, with
less resistance being provided towards the edges of the
helical portion, for example by grading the wires with a
thickest wire in the middle and thinner wires towards
30   the edges. Such an arrangement could ensure that the
shape of the expanded stent, when viewed in transverse
cross-section, does not have any sharp ridges or grooves
and ideally corresponds closely to a circle.

In a modified embodiment a helical portion is
35   formed by a single helically arranged wire 8 to produce
a stent of substantially circular cross-section. The
single wire can provide resistance to longitudinal

extension during expansion of the stent and cause it to
define a lumen with a helical centre line. A circular
cross-sectional shaped stent can still provide the
desired swirl inducing effect providing the centre line
5   of the lumen is helical.

Figures 4 and 5 show an embodiment of a stent of
the so-called helical spiral type. In this case the
basic stent design consists of a wire 10 in a wave form,
shown at 12, with that wave form extending in the manner
10   of a coil from one end of the stent to the other.
Longitudinally adjacent waves of the wave form 12 are
joined by connecting elements 14. In the expanded
condition the wavelength of the waves is, for most of
the circumference of the stent, a distance D. In the
15   region of the helical portion 6 this wavelength is
reduced to less than D. The effect of the reduced
wavelength is to cause the lumen of the fluid conduit in
which the stent is expanded to adopt the desired
configuration for promoting swirl flow in the lumen of
20   the fluid conduit.

In the collapsed condition of the stent of Figures
4 and 5 the wavelength of the waves of the wave form 12
is reduced throughout the stent. During expansion the
wavelength in the region of the helical portion 6
25   increases least. Extension in the circumferential
direction is resisted by the helical portion 6. This
could for example be achieved providing that the natural
shape of the waves in the helical portion 6 is one
having a smaller wavelength than D. This may be
30   appropriate for example if the stent is made by being
cut out from a metal sheet or tube.

Another way of achieving the reduced
circumferential expansion in the region of the helical
portion 6 would be to provide short bridges 16 between
35   circumferentially adjacent portions of the wave in the
helical portion 6. Such a bridge 16 is shown in Figure
5. Further bridges would be provided at intervals along

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the helical portion.

Figure 7 shows a stent of the closed cell type with "v" hinges between adjacent cells. In this case the helical portion 6 is provided by forming a helical line of cells 18 which are smaller than the other cells 20. When the stent is expanded, either by a balloon, or by the elastic or shape-memory properties of the material from which the stent is formed, the cells 20 expand to a predetermined size. The cells 18 expand to a smaller predetermined size and hence resist extension. As with the other stents, the result is that the lumen of the fluid conduit in which the stent is expanded adopts a configuration promoting swirl flow.

The various stents shown and described are provided with a single helical portion 6. However, other numbers of helical portions could be provided. Preferably the stents are non-rotationally symmetrical (rotational symmetry of order 1), as this can ensure that the centre line of the expanded stent follows a helical path.

Figure 14 shows an internal stent 12 for use in a graft vessel or an intact vessel. The stent 12 is fabricated from a linked wire mesh and has a helical form along substantially the whole length of the stent. The material used is preferably a shape memory alloy to facilitate insertion of the stent.

Figure 15 shows an alternative embodiment of an internal stent 12, in which the linked wire mesh has a helical tubing portion 1 only over a short region at one end thereof.

Figure 16 shows the stent 12 located in a graft 14 post insertion. The graft 14 surgically attached to an artery 6 has been shown transparent for purposes of illustration, to show the internally located, part helical wire mesh stent in-situ.

In the case of the internal stents of Figures 14, 15 and 16, in order to avoid the mesh itself forming a honeycomb of stagnant regions, a modification may

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involve providing the mesh with a smooth internal
lining. Alternatively, an inner layer of the stent may
be helically wound, without linkages, as described in WO
01/45593.

5   The helical form of the stents is arranged to
promote swirl flow and thereby minimise flow instability
and development of pathology.

The stents shown in Figures 14 and 15 are defined
within an envelope with a curved longitudinal axis.

10   They are generally arch shaped. Such an arch may curve
in a single plane or may itself be non-planar, in which
case the non-planarity should promote swirl flow in the
same direction as the helix.

The stents need not be arch shaped; they may

15   instead have a generally straight axis, as shown for
example in Figure 17. The stent of Figure 17 has a
straight central longitudinal axis 30, with a helical
centre line 40 which undergoes about half of one turn.
The low amplitude of the helix of the stent means that

20   it is close to a cylindrical shape and can therefore be
used in procedures where conventional stents would
previously have been used. However, this is achieved
without departing from a circular cross-sectional shape
and without using helical ribs or other projecting

25   formations. It is expected that the vessel into which
the stent is inserted will be able to adopt the shape
defined by the stent and therefore benefit from swirl
flow. In other embodiments, the helical centre line may
undergo more than half of one turn, and indeed more than

30   one or more turns.

The stent of Figure 17 may be useful as an arterial
stent where there is thrombosis or stenosis of for
example coronary arteries.

Figure 8 shows the result of an experiment carried

35   out on a toy balloon 55. The balloon was of the
elongated type. It was supported, without being
inflated, on a cylindrical rod and a plastic strip 51

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cut from another balloon was glued onto the outside of
the supported balloon to form a longitudinally and
circumferentially extending helical strip 6. A straight
line 50 was drawn along the balloon. After the glue had
set, the balloon was inflated and the inflated balloon
is shown in Figure 8.

It will be seen that the inflated balloon 55 has a
helical lumen. As with the stents, it has a helical
centre line 40, which follows a helical path about a
longitudinal axis 30. The longitudinal axis is at the
centre of an imaginary cylindrical envelope 20 within
which the balloon is contained. The amplitude A of the
helix is shown in Figure 8.

It will be noted that after inflation the straight
line 50 adopts a wave shape which remains consistently
along the same side of the balloon, so that the entire
line 50 remains visible in the elevation view of Figure
8. This indicates that the balloon has gone from the
collapsed condition to the inflated condition without
any significant twisting. There is no net twisting
along the length of the balloon. A similar effect in an
expanding stent in accordance with the preferred
embodiments of the invention means that as the stent
expands and engages the inside of a fluid conduit in
which it is sited it does not impose excessive torsional
loads on that conduit. This is beneficial in the case
of the conduit being a blood vessel, for example, since
torsion is resisted by the external tethering of the
blood vessel.

Thus in the preferred embodiments the stents expand
from the collapsed condition to the expanded condition
without substantial twisting. The lack of twisting of
the stent also enables it to have a plurality of turns
without causing e.g. a blood vessel to twist during
expansion, such twisting being undesirable because of
the tethering of the blood vessel.

The balloon of Figure 8 starts as a cylindrical

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membrane with a helical portion which is of greater (in
this case double) wall thickness than the rest of the
balloon. During inflation the thicker helical portion
will tend to resist extension in all directions,
5   including circumferential and longitudinal directions,
thereby influencing the shape of the expanded balloon.
Instead of adopting the normal cylindrical shape, the
balloon forms a shape with a helical centre line 40.

Figure 8 shows that the amplitude A achieved by the
10   helical portion is much greater than would be achieved
by simple rotation of a non-circular cross-section. The
diameter of the envelope 20 is substantially greater
than the diameter of the balloon. The same effect is
obtained for an expanded stent outer wall or the wall of
15   a balloon used in a balloon expandable stent.

In another experiment, a plastic strip 52 was made
with a tapered width, rather than with parallel side
edges. It was found that the amplitude A of the helical
centre line 40 was larger where the width of the strip
20   was wider. This is shown in Figure 9. A thinner strip
tends to cause less deviation of the cross-sectional
shape of the balloon from a circular shape.

The shape of the expanded experimental balloon
membranes may be considered as analogous to that of an
25   expanded stent outer wall or the wall of a balloon used
in a balloon expandable stent. Considering therefore
the inside of the helical balloon as a lumen or flow
path, it will be appreciated that a helical lumen is
obtained, giving the desirable flow properties discussed
30   above, without the use of ribs, vanes or other flow
guides protruding into the flow.

The experimental results thus show that by
introducing a helical portion which resists extension
during expansion of a stent, when expanded the stent
35   will adopt a shape causing a fluid conduit which it
supports to have a helical lumen, thereby promoting
swirl flow. The effect observed in the balloons of

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Figures 8 and 9 may be obtained in a main stent body, either self-expanding or balloon expandable, and/or in a balloon which is used to expand a balloon expandable stent.

5   Figure 10 shows a balloon expandable stent 2. A balloon 55 is provided with a helical strip 6. Upon inflation, the balloon causes the stent 2 to adopt the desired helical geometry, expanding to a shape as shown in the experimental balloon of Figure 8. The stent is

10   designed to deform plastically so that it holds to the shape supporting a conduit e.g. blood vessel so as to have a helical flow lumen.

It will be noted that in the preferred embodiments the stent does not rely on the use of thicker wires

15   which themselves provide ribs or flow guides in an otherwise circular cross-section lumen. Rather, the shape of the lumen is modified by the resistance of the helical portion to extension.

The tubing portion 1 shown in Figure 11 has a

20   circular cross-section, an external diameter D_E, an internal diameter D_I and a wall thickness T. The tubing is coiled into a helix of constant amplitude A (as measured from mean to extreme), constant pitch P, constant helix angle θ and a swept width W. The tubing

25   portion 1 is contained in an imaginary envelope 20 which extends longitudinally and has a width equal to the swept width W of the helix. The envelope 20 may be regarded as having a central longitudinal axis 30, which may also be referred to as an axis of helical rotation.

30   The illustrated tubing portion 1 has a straight axis 30, but it will be appreciated that in alternative designs the central axis may be curved. The tubing portion has a centre line 40 which follows a helical path about the central longitudinal axis 30.

35   It will be seen that the amplitude A is less than the tubing internal diameter D_I. By keeping the amplitude below this size, the space occupied by the

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tubing portion can be kept relatively small, whilst at the same time the helical configuration of the tubing portion promotes swirl flow of fluid along the tubing portion.

5

EXAMPLE 1

Experiments were carried out using polyvinyl chloride tubing with a circular cross-section.
10   Referring to the parameters shown in Figure 12 the tubing had an external diameter D_E of 12mm, an internal diameter D_I of 8mm and a wall thickness T of 2mm. The tubing was coiled into a helix with a pitch P of 45mm and a helix angle θ of 8°. The amplitude A was
15   established by resting the tubing between two straight edges and measuring the space between the straight edges. The amplitude was determined by subtracting the external diameter D_E from the swept width W:

20

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$$2A = W - D_E$$

So:

$$A = \frac{W - D_E}{2}$$

In this example the swept width W was 14 mm, so:

$$A = \frac{W - D_E}{2} = \frac{14-12}{2} = 1\ mm$$

As discussed earlier, "relative amplitude" A_R is defined as:

$$A_R = \frac{A}{D_I}$$

In the case of this Example, therefore:

$$A_R = \frac{A}{D_I} = \frac{1}{8} = 0.125$$

Water was passed along the tube. In order to observe the flow characteristics, two needles 80 and 82 passing radially through the tube wall were used to inject visible dye into the flow. The injection sites were near to the central axis 30, i.e. at the "core" of the flow. One needle 80 injected red ink and the other needle 82 blue ink.

Figure 11 shows the results of three experiments, at Reynolds numbers R_E of 500, 250 and 100 respectively. It will be seen in all cases that the ink filaments 84 and 86 intertwine, indicating that in the core there is swirl flow, i.e. flow which is generally rotating.

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EXAMPLE 2

The parameters for this Example were the same as in
Example 1, except that the needles 80 and 82 were
arranged to release the ink filaments 84 and 86 near to
the wall of the tubing. Figure 13 shows the results of
two experiments with near-wall ink release, with
Reynolds numbers R_E of 500 and 250 respectively. It will
be seen that in both cases the ink filaments follow the
helical tubing geometry, indicating near-wall swirl.
Furthermore, mixing of the ink filaments with the water
is promoted.

It will be appreciated that this invention, in its
third and fourth aspects, is concerned with values of
relative amplitude A_R less than or equal to 0.5, i.e.
small relative amplitudes. In a straight tubing portion
both the amplitude A and the relative amplitude A_R equal
zero, as there is no helix. Therefore, with values of
relative amplitude A_R approaching zero, the ability of
the tubing portion to induce swirl will reduce. The
lowest workable value of relative amplitude A_R for any
given situation will depend on the speed of flow and the
viscosity and density of the fluid (i.e. Reynolds
number) and on the pitch (helix angle) and the
particular use of the tubing portion. Relative
amplitudes of at least 0.05, 0.10, 0.15, 0.20, 0.25,
0.30, 0.35, 0.40 or 0.45 may be preferred.